

REMARKS

After entry of this Amendment, the pending claims are: claims 54, 56, 57, 59-79. The Office Action dated October 4, 2007 has been carefully considered. Claims 54, 56, 57, 59 and 60 have been amended. Claims 78 and 79 have been added. Claims 55 and 58 have been canceled. Claims 1-53 were previously canceled. Support for the amendment to claims 54, 56, 57, 59 and 60 and for newly added claims 77 and 78 can be found throughout the Specification and Drawings and specifically in paragraph Nos. [0047]-[0050]. As such, no new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated October 4, 2007, the Examiner:

- objected to the drawings for containing incorrect reference numbers;
- rejected claims 56 and 57 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement; and
- rejected claims 54-76 under 35 U.S.C. 103(a) as being unpatentable over the published article *Contact of Hydroxyapatite Spacers with Split Spinous Processes in Double-Door Laminoplasty for Cervical Myelopathy* by Shigery Hirabayashi and Kiyoshi Kumano (“Hirabayashi”) in view of U.S. Patent No. 6,277,149 to Boyle *et al.* (“Boyle”) and in further view of U.S. Patent No. 6,511,509 to Ford *et al.* (“Ford”).

DRAWINGS

The drawings were objected to for containing incorrect reference numbers. Specifically, the depiction of reference numbers 6a and 6b in Figures 1C, 2A and 2B were objected to for being inconsistent. A corrected Figure 2A is attached hereto. Withdrawal of this objection is respectfully requested.

DEPENDENT CLAIM 56 AND 57

Dependent claims 56 and 57 were rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement. Specifically, dependent claims 56 and 57 were rejected for containing subject matter which was not described in the specification in a way to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. In particular, the Examiner rejected the specified ranges stating that one could not arbitrary select a range and compare it to another range in order to calculate a ratio.

Dependent claim 56 has been amended to recite a depth D to thickness T ratio of approximately 4:1 to approximately 8:1. As provided in the specification, the “depth ‘D’ preferably should be between about 6.5 mm to about 7.5 mm. The thickness of wall 45 preferably should be from between about 1.00 to about 1.50 mm.” It is respectfully submitted that these dimensional ranges result in the claimed ratio, rounded to the nearest whole number – 4:1 (6.5 mm : 1.5 mm) to 8:1 (7.5 mm : 1.00 mm). Moreover, it is respectfully submitted that one of ordinary skill in the art would recognize that the Applicants were in possession of the claimed ratios at the time the application was filed as they represent the ratios of the largest and smallest depth D to thickness T dimensions provided in the specification.

Similarly, dependent claim 57 has been amended to recite a width W to thickness T ratio of approximately 6:1 to approximately 12:1. As provided in the specification, the “Width ‘W’ preferably should be between about 10 mm to about 11.5 mm ... The thickness of wall 45 preferably should be from between about 1.00 to about 1.50 mm.” It is respectfully submitted that these dimensional ranges result in the claimed ratio, rounded to the nearest whole number – 6:1 (10 mm : 1.5 mm) to 12:1 (11.5

mm : 1.0 mm). Moreover, it is respectfully submitted that one of ordinary skill in the art would recognize that the Applicants were in possession of the claimed ratios at the time the application was filed as they represent the ratios of the largest and smallest width W to thickness T dimensions provided in the specification.

Withdrawal of these rejections and allowance of claims 56 and 57 is respectfully requested.

INDEPENDENT CLAIM 54

Independent claim 54 has been rejected as being unpatentable over Hirabayashi in view of Boyle and in further view of Ford. As amended, independent claim 54 recites, *inter alia*, an implant comprising a thin-walled tubular allograft body, the thin wall tubular body including a first end, a second end, an outer surface, a bore defining an inner surface, and a thin wall extending between the outer surface and the inner surface, wherein the wall has a thickness T between about 1.00 mm to about 1.50 mm.

It is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, teach, disclose, or suggest a thin-walled tubular body. Moreover, since neither Hirabayashi, Boyle or Ford, either alone or in combination, teach, disclose, or suggest a thin-walled tubular body, it is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, teach, disclose, or suggest a thin-walled tubular body having a thin wall extending between an outer surface and an inner surface, wherein the wall has a thickness T between about 1.00 mm to about 1.50 mm.

As admitted by the Examiner, Hirabayashi does not disclose an allograft thin-walled tubular body having an outer surface and a bore defining an inner surface. Rather, the Examiner relies upon Boyle and/or Ford to disclose an allograft body having a central bore defining an inner surface. It is respectfully submitted that neither Boyle and/or Ford overcome the shortcomings of Hirabayashi since both Boyle and Ford fail to disclose, teach or suggest a thin walled tubular body. Boyle and Ford both disclose an allograft spacer sized and configured for insertion in-between adjacent vertebrae. This is an important distinction as the requirements for an intervertebral implant are different from the requirements of an implant sized and configured for a laminoplasty procedure. The allograft spacers of Boyle and Ford include top and bottom bone engaging surfaces for contacting the endplates of adjacent vertebrae. The spacers further include a central hollow bore extending from the top bone engaging surface to the bottom bone engaging surface. It is respectfully submitted that neither Boyle or Ford disclose a thin-walled tubular body. Rather, it is respectfully submitted that the wall in Boyle and Ford is relatively thick and must be so in order to support the anticipated loads.

Moreover, it is respectfully submitted that since neither Boyle or Ford disclose a thin-walled tubular body, they can not disclose, teach or suggest a thin walled tubular body having a thin wall extending between an outer surface and an inner surface, wherein the wall has a thickness T between about 1.00 mm to about 1.50 mm.

Therefore, it is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, disclose, teach or suggest all of the limitations of newly added independent claim 54 since neither reference discloses a thin-walled tubular body having a thin wall extending between an outer

surface and an inner surface, wherein the wall has a thickness T between about 1.00 mm to about 1.50 mm.

For at least the above-identified reasons, it is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 54. Thus, it is respectfully submitted that independent claim 54 is allowable over the cited prior art. Allowance of independent claim 54 is respectfully requested.

Furthermore, as claims 56, 57, and 59-77 all depend from independent claim 54, it is submitted that these claims are equally allowable. Allowance of claims 56, 57, and 59-77 is also respectfully requested.

NEWLY ADDED INDEPENDENT CLAIM 78

Newly added independent claim 78 recites, *inter alia*, an implant comprising a thin-walled tubular allograft body, the thin wall tubular body including a longitudinal axis, a first end, a second end, an outer surface, a bore defining an inner surface, and a thin wall extending between the outer surface and the inner surface, wherein the wall has a thickness T and the implant further comprises a width W and a depth D, wherein the wall of the implant has a depth D to thickness T ratio of approximately 4:1 to approximately 8:1.

In an effort to expedite prosecution of newly added independent claim 78, the Applicants hereby offer the following Remarks regarding Hirabayashi, Boyle and Ford.

As previously mentioned, it is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, teach, disclose, or suggest a thin-walled tubular body.

Moreover, it is respectfully submitted that there is absolutely no disclosure, teaching or suggestion in Hirabayashi, Boyle or Ford of a depth D to thickness T ratio of approximately 4:1 to approximately 8:1.

For at least the above-identified reasons, it is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 78. Thus, it is respectfully submitted that independent claim 78 is allowable over the cited prior art. Allowance of independent claim 78 is respectfully requested.

NEWLY ADDED INDEPENDENT CLAIM 79

Newly added independent claim 79 recites, *inter alia*, an implant comprising a thin-walled tubular allograft body, the thin wall tubular body including a longitudinal axis, a first end, a second end, an outer surface, a bore defining an inner surface, and a thin wall extending between the outer surface and the inner surface, wherein the wall has a thickness T and the implant further comprises a width W and a depth D, wherein the wall of the implant has a depth W to thickness T ratio of approximately 6:1 to approximately 12:1.

In an effort to expedite prosecution of newly added independent claim 79, the Applicants hereby offer the following Remarks regarding Hirabayashi, Boyle and Ford.

As previously mentioned, it is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, teach, disclose, or suggest a thin-walled tubular body.

Moreover, it is respectfully submitted that there is absolutely no disclosure, teaching or suggestion in Hirabayashi, Boyle or Ford of a width W to thickness T ratio of approximately 6:1 to approximately 12:1.

For at least the above-identified reasons, it is respectfully submitted that neither Hirabayashi, Boyle or Ford, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 79. Thus, it is respectfully submitted that independent claim 79 is allowable over the cited prior art. Allowance of independent claim 79 is respectfully requested.

CONCLUSION

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

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Respectfully submitted,

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